

REMARKS

The specification has been amended to correct minor errors. With the change in the claim to priority, the claims have been amended to conform to the language found in the first priority document, U.S. Provisional Application No. 60/115,877. The claims have also been amended to be directed to the elected subject matter. They have not been made for reasons related to patentability. Applicants maintain the restriction requirement and the rejection under 35 USC §112 are improper and reserve the right to pursue the original claims in a subsequent or copending application.

Information Disclosure Statement

Applicants have presented new 1449 forms for the references that were not initialed. Titles and filing dates have been inserted for Cite nos. AA-BM.

Certain citations within the IDS filed on December 23, 2002 do not have titles or publication dates. After numerous attempts, it does not appear that these citations can be presented in an appropriate format to be initialed and included on the front page of the patent. Two of the cited references, Iranian Patent 26555 (IDS cite BO) and Lebanese Patent No. 6124 (IDS cite No. BP) were filed on January 13, 2000 and January 12, 2000, respectively, which is after the priority date for this application. The references with IDS cite nos. KY, KZ, LA, LB, LC and LD, are the results from searches performed on computer data bases on the dates identified. These documents were not published and they do not have titles but are presented to comply with the duty to disclose information under Rule 56. If the examiner can not initial these citations on the 1449 form, applicants request that examiner comment on the record as to whether the substance of any of these references was considered.

Election Restriction

Applicants submit that the elected Group [Group IV, drawn to compounds pharmaceutical compositions and methods of treating using compounds of formula I where A is L-M-L', wherein M is oxygen or sulfur, L is phenyl and L' is phenyl, pyridinyl or pyrimidinyl and B is phenyl substituted by a tert butyl group or trifluoromethyl group] be expanded to encompass subject matter independent of the substituents on L and B and to encompass additional heterocycles for B and L. Such compounds clearly have a common structural core which is the urea skeleton defined

by the values B, L, M, and L', as well as the substituent: C(O)R_aR_b bonded to L'.

Furthermore, Applicants submit that it would not be an undue burden to examine the full scope of the subject matter claimed in that all groups were searched and examined by the U.S. Patent Office in the International Application and the Examiner has performed related searches in the following applications; U.S. Application Nos. 09/948,915, 09/773,675, 09/773,659, 09/773,604, 09/773,658 and 09/773,672. For the reasons indicated above, Applicants submit the full scope of the pending claims as amended should be examined.

Rejection Under 35 U.S.C §112, First Paragraph

Applicants submit that the original claims satisfy the requirements of 35 U.S.C §112, first paragraph

The Final Office Action maintains the allegation that the specification does not reasonably provide enablement for all of the compounds encompassed by the claims. More particularly it is alleged that the specification does not provide enablement for any organic compounds with 1-40 carbon atoms or 1-24 carbon atoms. These phrases are not used alone in defining the compounds of this invention. The phrase "up to 40 carbon atoms" is used in defining "A" which is further defined as being of the formula " $-L-(M-L^1)_q$." Similarly the phrase "carbon based moieties of up to 24 carbon atoms optionally containing hetero atoms O, N and S" serves as only part of a general definition to define "A" and "B" of formula I. This phrase is used to define substituents that appear on "A" and "B." When considering the full definition of the moiety "A" it is sufficiently specific that to prepare compounds not illustrated would require no more than routine experimentation, if any at all.

The specification provides ample guidance on how to prepare compounds encompassed by the original claims as well as the amended claims. There are a number of exemplified compounds which have a moiety "A" with over 20 carbon atoms and some have over 25 carbon atoms with hetero atoms (see examples 40 and 76). There are also a number of the exemplified compounds which have substituents with over 10 carbon atoms and the urea of example 40 has over 15 carbon atoms with heteroatoms. The specification discloses the procedures used to synthesize the exemplified compounds. (see specification page 53, line 18 to page 75, line 5). Through these examples the specification teaches how to prepare ureas with large

substituents and large "A" moieties. With these disclosures, one skilled in the art can vary the identity of the substituents as well as the moiety "A" itself without undue experimentation. The specific reaction schemes on page 17, line 5 to page 53, line 14), and the general reaction schemes on page 7, line 1 to page 10, line 5) provide additional guidance to enable one skilled in the art to make the compounds claimed. In addition, the specification points to the following references which describe how to prepare starting materials:

- March, *Advanced Organic Chemistry*, 3rd Ed.; John Wiley: New York (1985);
- Larock. *Comprehensive Organic Transformations*;
VCH Publishers: New York (1989);
- Rylander. *Hydrogenation Methods*; Academic Press: London, UK (1985); and
- Seyden-Penne. *Reductions by the Alumino- and Borohydrides in Organic Synthesis*;
VCH Publishers: New York (1991); (see page 7, lines 8-19).

This amount of guidance is more than adequate under the law to enable the preparation of the compounds claimed.

Even absent such disclosure, the courts have placed the burden upon the PTO to provide evidence shedding doubt on the disclosure that the invention can be made and used as stated; see, e.g., *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971) (holding that how an enabling teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance.) The disclosure must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statement contained therein. See *In re Marzocchi*, supra. No such evidence or reason for doubting Applicants' disclosure is provided.

Additionally, "the [enablement] requirement is satisfied if, given what they [, those or ordinary skill in the art,] already know, the specification teaches those in the art enough that they can make and use the invention without 'undue experimentation.'" See *Amgen v Hoechst Marion Roussel*, 65 USPQ2d 1385 (CA FC 2003). Making the compounds of the claimed invention would be routine for those of ordinary skill in the art in view of applicant's disclosure. Explicitly providing examples for preparing every species encompassed by the claims is not necessary to enable the same. See, for example, *Spectra-Physics v Coherent*, 827 F.2d 1524, 3 USPQ2d 1737 (Fed. Cir. 1987) ("A patent need not teach, and preferably omits,

what is well known in the art"); *In re Howarth*, 654 F.2d at 105, 210 USPQ 689 (CCPA 1981) ("An inventor need not ... explain every detail since he is speaking to those skilled in the art."); *In re Gay*, 309 F.2d 769, 774, 135 USPQ 311 (CCPA 1962) ("Not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be.")

There is no requirement that an applicant provide examples directed to the preparation of each and every species of a claimed invention. See, for example, *In re Angstadt*, 537 F.2d at 502-03, 190 USPQ 214 (CCPA 1976) (deciding that applicants "are *not* required to disclose *every* species encompassed by their claims even in an unpredictable art"); *Utter v Higara*, 845 F.2d at 998-99, 6 USPQ2d 1714 (CAFC 1988) (holding that a specification may, within the meaning of Section 112, Para. 1, enable a broadly claimed invention without describing all species that claim encompasses). Instead, as discussed earlier, there is no requirement for any examples. See, for example, *Marzocchi*, *supra*, stating that "an enabling teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance." The MPEP also agrees by stating that "compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed." See MPEP § 2164.02.

The PTO has failed to meet its burden of establishing that the disclosure does not enable one skilled in the art to make the compounds recited in the claims. Instead of relying on proper probative evidence, the rejection is improperly based on the bare allegation that the disclosure does not provide enablement. No evidence has been presented which would demonstrate that the guidance provided by the specification is inadequate to enable the preparation of the claimed compounds without undue experimentation.

It is alleged that the specification does not provide a written description of the moieties and substituents as carbon based moieties with 24 or up to 40 carbon atoms along with other hetero atoms. While this language is broad, one skilled in the art can ascertain whether a substituent is carbon based and falls with the size limits prescribed and therefore will recognize what applicants invention is. While the definitions for these substituents and moieties are broad, they are not indefinite.

The language does not encompass any number of organic groups. These groups can have up to 40 carbon atoms, which is a clear limitation. The numerous examples of the substituents and ring structures support the scope of this language. The identity of the compounds claimed is based on the urea group and "A" of the formula $-L(M-L^1)_q$. Applicants maintain the broad language defining the substituents and moiety B is adequate and necessary to define the full scope of the invention.

Therefore, Applicants respectfully submit the reasons given for the rejection under 35 USC §112, first paragraph are not viable and the rejection should be withdrawn. . Applicants reserve the right to pursue the original claims in subsequent or copending applications.


Double Patenting

The claims define a subgeneric group of compounds consistent with Group IV of the Restriction Requirement. Any rejection based on double patenting must be consistent with the finding that this subject matter is patentably distinct

Based on the above remarks, Applicants submit that the pending claims are in a form suitable for allowance and consistent with the election requirement. Therefore, withdrawal of the rejections and allowance of these claims are earnestly solicited.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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